IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ASTRAZENECA AB, et al.	**:**	**CIVIL ACTION**
Plaintiffs,	**:**	
	:	
v.	**:**	
	:	
MUTUAL PHARMACEUTICAL	**:**	
COMPANY, INC.	**:**	
Defendant.	**:**	**NO. 00-4731**

Reed, S.J. **March 12, 2002**

MEMORANDUM

Presently before the Court in this patent case is the motion of plaintiffs AstraZeneca AB, Aktiebolaget Hässle, KBI-E Inc., KBI Inc. and AstraZeneca LP (collectively referred to as "Astra") for summary judgment (Document No. 50) pursuant to Federal Rule of Civil Procedure 56(c). Astra requests that this Court rule that defendant Mutual Pharmaceutical Company, Inc. ("Mutual") failed to provide notice required under the Hatch-Waxman Act, 21 U.S.C. § 355 (j)(2)(B)(i) and (ii), and its accompanying regulation, 21 C.F.R. § 314.95, and as a result of such failure, this Court should order Mutual to withdraw its Paragraph IV certification for each dosage form in its ANDA No. 75-896 and dismiss this action as moot upon such withdrawal. In the alternative, Astra moves this Court to order that Mutual inform the Food and Drug Administration ("FDA") that it has not fulfilled the notice requirement pursuant to 21 U.S.C. § 355 (j)(2)(B)(ii). Upon consideration of the motion, response and reply thereto, and for the reasons which follow, I will deny the relief sought by plaintiffs.

I. The Hatch-Waxman Act

Before addressing the background of this case, a general overview of the Hatch-Waxman Act will allow an understanding of the factual and procedural history of this case. The Hatch-

Waxman Act ("the Act") amended the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq., as well as the patent laws. See Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241, 1244 (Fed. Cir.), cert. denied, 531 U.S. 993 (2000). The Act allows a pharmaceutical manufacturer to submit an abbreviated new drug application ("ANDA") in order to seek expedited FDA approval of a generic version of a drug previously approved by the FDA (a "listed drug"). § 355 (j). In submitting an ANDA, the manufacturer may rely in part on the pioneer manufacturer's work by providing data demonstrating that the generic product is the bioequivalent of the previously approved drug.[1] § 355 (j)(2)(A).

A manufacturer submitting an ANDA must certify one of four statements concerning the applicable listed drug: (i) the listed drug is not patented; (ii) the listed drug's patent has expired; (iii) the expiration date of the listed drug's patent; or (iv) the listed drug's patent "is invalid or . . . it will not be infringed by the manufacture, use, or sale of the new drug" covered by the ANDA. § 355 (j)(2)(A)(vii)(I)-(IV). These are commonly referred to as Paragraph I, II, III and IV certifications. The first manufacturer to file a Paragraph IV certification gains a 180-day marketing exclusivity period during which no subsequent ANDA filer can obtain FDA approval. § 355 (j)(5)(B)(iv). If an ANDA is certified under Paragraph IV, as in the case before me, the applicant is required to notify the patent owners of the certification. § 355 (j)(2)(B). "Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." § 355 (j)(2)(B)(ii). See also 21 C.F.R. §

[1] A drug is bioequivalent to a listed drug if the extent and rate of absorption of the drug are not significantly different from that of the listed drug, 21 U.S.C. § 355(j)(8)(B)(i), or if the extent of absorption is not significantly different from that of the listed drug, and the drug's rate of absorption differs from that of the of the listed drug, and the difference on the rate is intentional, is reflected on the label, and is medically insignificant for the drug, 21 U.S.C. § 355(j)(8)(B)(ii).

314.95 (c) (6) ("The applicant shall include in the detailed statement: (i) For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed.(ii) For each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.").

The ANDA is immediately effective only if the patent holder does not bring a law suit for infringement within 45 days of receiving the notice. § 355 (j)(5)(B)(iii). If the patentee files suit, the FDA may not approve the ANDA until the patent expires, judicial resolution of the infringement action, a judicial determination that the patent is either invalid or unenforceable, or thirty months from the patentee's receipt of notice, whichever occurs first. Id. See also Ben Venue Lab., Inc. v. Novartis Pharm. Corp., 146 F. Supp. 2d 572, 579 (D.N.J. 2001) (purpose of 30-month stay not necessarily to prolong the monopoly held by the pioneer manufacturer, but to create a window of time to allow a court to resolve the issue of infringement). The Court in which the suit is pending, has the authority to order a shorter or longer stay on the approval time, if "either party to the action fail[s] to reasonably cooperate in expediting the action." Id. See also Mylan Pharm., Inc. v. Thompson, 268 F.3d 1323, 1326 (Fed. Cir. 2001). These provisions afford the pioneer manufacturer the first opportunity to bring an infringement action against the ANDA manufacturer and may substantially delay the ANDA approval during the pendency of the litigation. See Mylan, 268 F.3d at 1327.

Under 35 U.S.C. § 271 (e)(2), "a highly artificial act of infringement" occurs when an ANDA is submitted containing a Paragraph IV certification that is in error as to whether the manufacture, use, or sale (none of which has actually occurred) of the new drug violates the patent in question. Eli Lilly and Co.v. Medtronic, 496 U.S. 661, 678, 110 S. Ct. 2683, 2692, 110

L.Ed.2d 605 (1990). It is not only the type of infringement that is "artificial," the consequences of such infringement are as well. See id. Monetary damages are only allowed if there has actually been "commercial manufacture, use, or sale." Id. (citing 35 U.S.C. § 271 (e)(4)). The obvious purpose of defining the ANDA submission as an act of infringement is to allow judicial adjudication of the issue. See id. If the court concludes that the patent is valid and that infringement would occur, the ANDA certification is deemed incorrect, and the patent holder is entitled to an order that FDA approval may not be effective until the patent expires. See Bayer AG, 212 F.3d at 1245. The statute does not set forth a specific remedy to benefit the patent holder if the ANDA filer provides inadequate notice.

II. Background[2]

On June 6, 2000, Mutual filed an ANDA seeking FDA approval to market a generic 10 mg. felodipine tablet. The ANDA was subsequently amended to include a 1.5 mg. tablet and a 5 mg. tablet. The ANDA contained three Paragraph IV certifications; one for each tablet, relating to U.S. Patent No. 4,803,081 ("the '081 patent"), which is held by Astra. Mutual sent three notice letters dated August 7, 2000 (10 mg. tablet), August 15, 2000 (5 mg. tablet), and August 31, 2000 (2.5 mg. tablet). Each letter recited Claim 1, the only independent claim of the '081 patent, which provides:

> 1. A solid preparation providing extended release of an active compound with very low solubility in water comprising a solution or dispersion of an effective amount of the active compound in a semi-solid or liquid *nonionic solubilizer*, wherein the amount by weight of the active compound, and a release controlling system to provide extended release.

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[2] The facts laid out in this opinion are based on the evidence of record viewed in the light most favorable to defendant Mutual, the nonmoving party, as required when considering a motion for summary judgment. See Carnegie Mellon Univ. v. Schwartz, 105 F.3d 863, 865 (3d Cir. 1997).

(Def.'s Exs. 5-7; Pls' Ex. 1) (emphasis added). Following the recitation of Claim 1, Mutual's notice letters directed to Astra include the following statement:

> Accordingly, all claims of the '081 patent require the presence of a semi-solid or liquid *nonionic solubilizer* in which the active compound is dispersed. The presence of this element in the claims was argued to be critical to the patentability of the invention. *Mutual's Felodipine ER tablets do not contain a nonionic solubilizer*.

(Id.) (emphasis added). The letters concluded with the following:

> Mutual hereby offers to supply to counsel for AstraZeneca copies of the relevant documents disclosing the formulation for Mutual's felodipine ER tablets product on an "outside-counsel-eyes-only" basis, for the sole purpose of verifying the accuracy of the assertion herein that Mutual's tablets for which approval is sought does not infringe the '081 patent.

(Id.)

On September 11, 2000, counsel for Astra wrote a letter to counsel for Mutual, providing that in Astra's view, the notice letters failed to include a "full and detailed explanation" as to how Mutual's product would not infringe upon the '081 patent. (Pls.' Ex. 26.) Counsel had a telephone conversation the following day. (Def.'s Ex. 4; Pls.' Ex. 27.) On September 15, 2000, Astra's counsel wrote another letter reiterating the same position taken in the letter of September 11, 2000. (Pls.' Ex. 27.) On September 12, 2000, Mutual certified to the FDA that notice had been provided as required under the law. (Pls.' Ex. 27.) On September 18, 2000, Astra exercised its rights and brought the present infringement action. On October 3, 2000, Mutual's counsel wrote a letter, claiming, *inter alia*, that "the letters clearly and concisely provide the legal basis underlying the Paragraph IV filing. . . .," and that the present action was filed in bad faith; Mutual also reiterated its offer to provide the formulations. (Def.'s Ex. 4.) Astra, it appears, never took Mutual up on its offer to provide the formulations.

In the course of discovery, plaintiffs were able to unearth a more detailed explanation from Mutual as to why it believed that the Mutual felodipine tablets do not infringe on the '081 patent. Mutual's Vice-President of Research and Development, Dr. Spireas, developed Mutual's felodipine formulation which uses polyethylene glycol 400 ("PEG-400"). Dr. Spireas theorized that the use of PEG-400 would fall outside the scope of the patent. (Pls.' Ex. 7, Dep. of Andrew Argiriadi, Mutual's Business Development Manager, at 43.) Mutual does not dispute the fact that it had some concern that the use of PEG-400 could give rise to an infringement action. (Pls.' Ex 3, Dep. of Richard H. Roberts, President, Chief Executive Officer and Chairman of the Board of Mutual, at 141; Pls.' Ex 7, Dep. of Argiriadi at 75-76.) It appears that two law firms were contacted to pursue this issue; the second firm contacted wrote three opinion letters. (Pls.' Ex. 17, Opinion letter dated 11/17/99; Pls.' Ex 18, Opinion letter dated 10/6/99; Pls.' Ex. 20, Opinion letter dated 11/18/99; Pls.' Ex. 23, Opinion letter dated 6/6/00.) The opinion letters in essence detail, *inter alia*, the potential arguments which can be made that the phrase "semi-solid or liquid nonionic solubilizer" should not include PEG-400. While this Court makes absolutely no determination as to the merits of defendant's position, it is manifestly clear from these opinion letters that the argument that PEG-400 does not infringe on the '081 patent is premised on a particular construction of the claim, as interpreted through the actual claim language, the specification and the prosecution history.

III. Standard

In deciding a motion for summary judgment under Rule 56 of the Federal Rules of Civil Procedure, the "test is whether there is a genuine issue of material fact and, if not, whether the moving party is entitled to judgment as a matter of law." Medical Protective Co. v. Watkins, 198

F.3d 100, 103 (3d Cir. 1999). "As to materiality, the substantive law will identify which facts are material. Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986). Furthermore, "summary judgment will not lie if the dispute about a material fact is 'genuine,' that is, if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Id. at 250.

On a motion for summary judgment, the facts should be reviewed in the light most favorable to the non-moving party. See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 587, 106 S. Ct. 1348, 89 L. Ed. 2d 538 (1986) (quoting United States v. Diebold, Inc., 369 U.S. 654, 655, 82 S. Ct. 993, 8 L. Ed. 176 (1962)). The nonmoving party "must do more than simply show that there is some metaphysical doubt as to the material facts," Matsushita, 475 U.S. at 586, and must produce more than a "mere scintilla" of evidence to demonstrate a genuine issue of material fact and avoid summary judgment. See Big Apple BMW, Inc. v. BMW of North America, Inc., 974 F.2d 1358, 1363 (3d Cir. 1992).

IV. Analysis

I begin by determining whether Mutual provided proper notice under the Hatch-Waxman Act. As detailed above, the notice must include "a full and detailed explanation" supporting the applicant's opinion that the patent is not valid or will not be infringed." 21 C.F.R. § 314.95(c)(6). As noted earlier, Mutual's notice, in relevant part, includes the following statement:

> Accordingly, all claims of the '081 patent require the presence of a semi-solid or liquid *nonionic solubilizer* in which the active compound is dispersed. The presence of this element in the claims was argued to be critical to the patentability

> of the invention. *Mutual's Felodipine ER tablets do not contain a nonionic solubilizer*.

(Def.'s Exs. 5-7; Pls' Ex. 1) (emphasis added). In addition, Mutual offered to disclose the felodipine formulation on an "outside-counsel-eyes-only" basis. (Id.) Mutual, in its letter to counsel for Astra dated October 3, 2000, noted "the letters clearly and *concisely* provide the legal basis underlying the Paragraph IV filing. . . ." (Def.'s Ex. 4) (emphasis added). Mutual also stresses that it repeatedly offered to disclose to Astra the formulation of its tablets, but Astra refused the offer. This offer to produce the formulation, however, does not amount to a statement, which is the legal requirement placed on defendant. I conclude that Mutual's "concise" explanation and its offer to disclose the felodipine formulation, in light of the existence of four opinion letters which focus on the whether PEG-400 would be considered a "semi-solid or liquid nonionic solubilizer," constitute a "full and detailed explanation" for Mutual's position that its product does not infringe on the '081 patent. Mutual's contention that through the notice letters it satisfied its obligation is at best disingenuous.

The much more troublesome question is whether plaintiffs have shown that Mutual's failure to *initially* give proper notice to plaintiffs constitutes an actionable element of plaintiffs' cause of action before this Court. Even plaintiffs concede that no court has been faced with a motion for summary judgment on the sole issue of failure to give proper notice under the Hatch-Waxman Act. Plaintiffs were have failed to cite a single case in which a court concluded that there is any remedy available to a patentee for such a violation, let alone ordered an ANDA filer to withdraw its Paragraph IV certification or to inform the FDA that it has not fulfilled the notice requirement. Plaintiffs have failed to present any legal authority from Congress, or regulators or

law review scholars which would support the relief they seek. Rather, plaintiffs turn to the following two cases to support their position.

In Yamanouchi Pharmaceutical Co., Ltd. v. Danbury Pharmacal, Inc., 231 F.3d 1339, 1347-48 (Fed. Cir. 2000), the Court of Appeals for the Federal Circuit held that it was not an abuse of discretion for the district court to determine that the Paragraph IV certification at issue was baseless and therefore could serve to qualify the case as "exceptional" and thus permit the award of counsel fees. In determining that the lower court had proper grounds for concluding that the notice was baseless, the Court of Appeals observed that the "notice does not present a *prima facie* case of invalidity." Id. at 1347. In Eli Lilly and Co. v. Zenith Goldline Pharm., Inc., No. IP 99-38-C H/K, 2001 WL 1397304, at *25 (S.D. Ind. Oct. 29, 2001), the Court determined that a particular two sentence notice was inadequate and in light of the evidence at trial, the defendant's infringement was willful and therefore the case qualified as "exceptional" thus allowing counsel fees to be awarded. Thus, in both Yamanouchi and Eli Lilly, the courts determined that an unfounded or deficient notice can lead to a finding of willful infringement which constitutes an exceptional case which permits the award of counsel fees. Neither case, however, concludes that poor notice, in and of itself, allows a court to order the withdrawal of an ANDA application or to notify the FDA that it has not fulfilled the notice requirement.

As outlined above, the provisions relating to notice are designed to grant the pioneer manufacturer the first opportunity to bring an infringement action against the ANDA manufacturer and may substantially delay the ANDA approval during the pendency of the litigation. See Mylan, 268 F.3d at 1327. A Paragraph IV certification allows a court to conclude that infringement has occurred despite the fact that the manufacturing, use, or sale of the generic

drug has *not* occurred. See Eli Lilly, 496 U.S. at 678, 110 S. Ct. at 2692. See also Ben Venue, 146 F. Supp. 2d at 578 (observing that the most notable effect of a Paragraph IV certification is that it creates the highly artificial infringement action). It seems plain that the purpose of the Paragraph IV notice is to alert the patentee to the possibility of infringement by the ANDA applicant so that the patentee can protect its interest by inquiry, investigation or litigation. Here, I conclude that Mutual's Paragraph IV notice has accomplished what the statute intended and note that plaintiffs have failed to cited to any legal authority which would indicate a different purpose for these provisions.

Plaintiffs have exercised their right to bring an infringement action against Mutual, and in the course of discovery, have clearly learned Mutual's position as to why it believes the felodipine tablets do not infringe upon the '081 patent. I agree that Mutual's conduct in sending an incomplete Paragraph IV notice to Astra has been far from exemplary; however, at the same time, plaintiffs have failed to show this Court that the defective notice has prejudiced them. I conclude that Astra has not shown prejudice; nor has Astra shown that inadequate notice constitutes an actionable violation under the Hatch-Waxman Act.

V. Conclusion

For the foregoing reasons, the relief sought by plaintiffs will be denied. An appropriate Order follows.

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ASTRAZENECA AB, et al.	**:**	**CIVIL ACTION**
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v.	**:**	
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MUTUAL PHARMACEUTICAL	**:**	
COMPANY, INC.	**:**	
Defendant.	**:**	**NO. 00-4731**

ORDER

AND NOW, this 12th day of March, 2002, upon consideration of the motion of plaintiffs AstraZeneca AB, Aktiebolaget Hässle, KBI-E Inc., KBI Inc. and AstraZeneca LP for summary judgment pursuant to Federal Rule of Civil Procedure 56(c), (Document No. 50), and the response and reply thereto, and having concluded for the reasons set forth in the foregoing memorandum that plaintiffs have failed to show that defendant's service of an inadequate notice constituted an actionable violation of the statute, it is hereby **ORDERED** that the motion is **DENIED**.

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LOWELL A. REED, JR., S.J.